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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,885	05/02/2001	Robert Nakayama	18564-005910	5809

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FOLEY AND LARDNER LLP
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WASHINGTON, DC 20007

EXAMINER

TALBOT, BRIAN K

ART UNIT	PAPER NUMBER
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1762

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary**Application No.**

09/847,885

Applicant(s)

NAKAYAMA ET AL.

Examiner

Brian K. Talbot

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/8/06 has been entered.

2. Claims 1-22 remain in the application.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. In light of the response filed 11/8/06, the 35 USC 112 first paragraph rejection has been withdrawn. In addition, the rejection including references Yamagishi et al. (5,756,879), Pace (4,454,007) or Kuroiwa et al. (5,296,819) has been withdrawn. However, the following rejection has been necessitated by the amendment.

Claim Rejections - 35 USC § 103

5. Claims 1-6,9,10 and 13-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. (5,571,401) or Lewis et al. (6,290,911) in combination with Hamamoto et al.

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(5,720,862), Yamamoto et al. (5,658,443), Say et al. (6,103,033) or Van Antwerp et al. (6,784,274).

Lewis et al. (5,571,401) or Lewis et al. (6,290,911) both teach sensor arrays for detecting analyte fluids. A sensing material comprising conducting and non-conducting material is blended to form the desired sensor. The sensing material is applied over a substrate having gold electrical contacts. The sensing material absorbs the detected material thereby providing a detectable response. The conductive material includes carbon black and the non-conducting polymers include a wide variety and can be applied by a variety of deposition processes including spraying and dipping. Arrays of sensors can be manufactured by these processes. The sensing material is applied by a variety of processes including spraying (abstract and col. 5, line 1 – col. 10, line 60).

Lewis et al. (5,571,401) or Lewis et al. (6,290,911) fail to teach coating a first conductive layer and then a non-conductive layer instead of a blended composition.

Hamamoto et al. (5,720,862) or Yamamoto et al. (5,658,443) both teach multilayered sensors having cover layers atop the sensing layer (Figure 1 in both references). Hamamoto et al. (5,720,862) further teaches apertures in the top cover layer to allow the sample applied atop the cover layer to pass and penetrate toward the reactive layer and the electrode system. The layers are applied and dried (col. 8, lines 5-55). Yamamoto et al. (5,658,443) further teaches that the top layer (8) allows infusion of the sample solution from the surface into the reaction layer. The layers are applied and dried. (col. 6, line 35 – col. 7, line 20).

Say et al. (6,103,033) teaches a process for producing electrochemical biosensors. The sensor includes electrodes, a sensing layer and a microporous barrier film which allows diffusion

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of the analyte into the sensing film to make contact with the electrodes (col. 6, line 25 - col. 15, line 40).

Van Antwerp et al. (6,784,274) teaches a hydrophilic coating for biosensors. The sensor is comprised of an electrode covered by a sensing layer which is covered by a hydrophilic layer which improves diffusion of the analyte to the sensing layer/electrodes 9col. 6, lines 20-60 and Figs 10A and 10B).

Therefore it would have been obvious for one skilled in the art at the time the invention was made to have modified Lewis et al. (5,571,401) or Lewis et al. (6,290,911) sensor manufacturing process by coating individual layers as evidenced by Hamamoto et al. (5,720,862), Yamamoto et al. (5,658,443), Say et al. (6,103,033) or Van Antwerp et al. (6,784,274) with the expectation of achieving the desired results.

With respect to claims 9 and 10 which recite the use of a robotic amateur. It has been well settled that the provision of mechanical or automated means to replace manual activity is held to have been an obvious modification of the art. *In re Venner 120 USPQ 192*

Claims 7,8,11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. (5,571,401) or Lewis et al. (6,290,911) in combination with Hamamoto et al. (5,720,862), Yamamoto et al. (5,658,443), Say et al. (6,103,033) or Van Antwerp et al. (6,784,274) further in combination with De Witt et al.(6,572,826).

Features described above concerning Lewis et al. (5,571,401) or Lewis et al. (6,290,911) in combination with Hamamoto et al. (5,720,862), Yamamoto et al. (5,658,443), Say et al. (6,103,033) or Van Antwerp et al. (6,784,274) are incorporated here.

Lewis et al. (5,571,401) or Lewis et al. (6,290,911) in combination with Hamamoto et al. (5,720,862), Yamamoto et al. (5,658,443), Say et al. (6,103,033) or Van Antwerp et al. (6,784,274) fails to teach using a mask to apply the films.

De Witt et al. (6,572,826) teaches a chemically sensitive sensor whereby the sensing material can be applied by spraying with the use of a mask to applying the coating to specific areas of the substrate (col. 8, lines 25-40).

Therefore it would have been obvious for one skilled in the art at the time the invention was made to have modified Lewis et al. (5,571,401) or Lewis et al. (6,290,911) in combination with Hamamoto et al. (5,720,862), Yamamoto et al. (5,658,443), Say et al. (6,103,033) or Van Antwerp et al. (6,784,274) multi-layered sensor by applying the layers with a masking means as evidenced by De Witt et al. (6,572,826) with the expectation of achieving a more precise and accurate deposition pattern.

Response to Arguments

6. Applicant's arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argued that the prior art fails to teach a non-conducting film atop the sensing film which is in contact with electrodes.

Features described above concerning Hamamoto et al. (5,720,862), Yamamoto et al. (5,658,443), Say et al. (6,103,033) or Van Antwerp et al. (6,784,274) all teach this limitation.

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Applicant argued that Hamamoto et al. (5,720,862), Yamamoto et al. (5,658,443) fail to teach the claimed structure as the insulating layer in underneath the sensing layer.

The Examiner disagrees. As detailed above, Hamamoto et al. (5,720,862) and Yamamoto et al. (5,658,443) both teach utilizing cover layer which allow the analyte to pass and contact with the sensing material.

Applicant argued that the prior failed to teach the post processing of the applied films.

These steps are disclosed in Hamamoto et al. (5,720,862), Yamamoto et al. (5,658,443) above. Furthermore, it is the Examiner's position that the use of post processing to dry/heat or fuse applied film is conventional in the art absent a showing of unexpected results garnered from this step.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian K. Talbot whose telephone number is (571) 272-1428. The examiner can normally be reached on Monday-Friday 6AM-3PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy H. Meeks can be reached on (571) 272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BK Talbot 1/23/07

Brian K Talbot
Primary Examiner
Art Unit 1762

BKT